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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/819,317	03/28/2001	Patrick L. Coleman	56066USA1A.002	4377	
7:	7590 06/10/2002 ttention: Christopher D. Gram				
Attention: Christopher D. Gram			EXAMINER		
	ectual Property Counsel Properties Company		MAUPIN, CHRISTINE L		
P.O. Box 33427 St. Paul, MN 55133-3427			ART UNIT	PAPER NUMBER	
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			DATE MAILED: 06/10/2002	3	

Please find below and/or attached an Office communication concerning this application or proceeding.

1		Application No.		Applicant(s)			
i		09/819,317		COLEMAN ET AL.			
	Office Action Summary	Examiner		Art Unit			
		Christine L. Maup		1637			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.							
<ul> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the maximum statutory.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>							
Status							
1)⊠	Responsive to communication(s) filed on <u>20 June 2001</u> .  This action is <b>FINAL</b> .  2b) This action is non-final.						
2a)☐	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>							
4)⊠ Claim(s) <u>1-25</u> is/are pending in the application.							
4a) Of the above claim(s) <u>12-15</u> is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.						
,	6)⊠ Claim(s) <u>1-11 and 16-25</u> is/are rejected.						
•	Claim(s) is/are objected to.						
• —	Claim(s) /2-15 are subject to restriction and/o	or election require	ement.				
Applicati	on Papers						
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
, —	The oath or declaration is objected to by the Ex	rannici.					
Priority under 35 U.S.C. §§ 119 and 120							
1	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)	a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) 🔀 Noti 2) 🔲 Noti	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449) Paper No(s)	4) 5) 6) \[ \int_{\infty}	Interview Summa Notice of Informa Other: Detailed A	ary (PTO-413) Paper No(s)  I Patent Application (PTO-152)  Action .			

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, and 16-25, drawn to a method of transferring molecule to a laminate, classified in class 430, subclass 53.
- II. Claims 12-15, drawn to a composition of film laminates, classified in class427, subclass 2.13.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition of group II may be made by Langmuir-Blodgett methods combined with gel transfer, SDS-polyacrylamide gel synthesis, or by synthetic reactions driven by an electro current.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Gram on 7 May 2002 a provisional election was made without traverse to prosecute the invention of group I, claims 1-11, and 16-25. Applicant in replying to this Office action must make affirmation of this

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election. Claims 12-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

All claims are drawn to the same claimed invention of (group II), 12-15, have been withdrawn from consideration.

## **Objections**

#### **Abstract**

The abstract of the inventions is objected to because it is not disclose the contents of the instant application in such a way that one skilled in the art would be able to determine the technical features.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

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Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

# Claim Rejections - 35 USC § 102

- b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-5, 7-11, 16-21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Halverson et al., WO9953319, 21 October 1999. Halverson et al., teaches a method of transferring molecule and preparing molecules for transfer molecules positioned within a matrix to a laminate comprising:
  - i) a substrate comprising a shrinkable polymeric film. Here, Halverson et al., states, "an elastomeric substrate is stretched and functionalized to create linking agents on the surface of the substrate" (Pg. 4, II, 16-18). Halverson et al., further states "The surface area of the substrate surface may be reduced, thereby increasing the density of the linking agents on the substrate" (Pg. 4, II, 13-14). Halverson et al., further states "the arrays of the of the present invention facilitate the affixation of a high concentration of reactant at each binding site, with all the attendant advantages of high density, including the ability to increase detection signal strength. And "an elastomeric substrate is stretched and functionalized to create linking agents on the surface of the substrate" (Pg. 4, II, 16-18).

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ii) a hydrogel disposed on the substrate, to transfer one or ,more molecules from the matrix to the laminate. Here, Halverson et al., states, "In one embodiment of the present invention, array includes a polymeric substrate and a coating comprising linking agents at least partially adhered thereto. (Pg. 3, II, 7-8) and "the high topological surface area arrays are particular useful in this regard. In addition, these high surface area arrays allow sample containing analyte(s) of interest to rapidly come in to contact with reactants, without the necessity of diffusing into a **thick** coating, such as a hydrogel (Pg. 3, II, 25-31) and "a heat shrinkable film is functionalized to create linking agents on the surface of the film for subsequent attachment of reactants" (Pg. 4, II, 11-13).

- 2. In regards to claim 2, Halverson et al., also states, "that a wide variety of coatings may be suitable for the present invention which encompasses the limitation of the generic term "hydrogel" such as an polyacrylamide gel, (Pg. 12, II, 23-30, and Example 11).
- 3. In regard to claim 3, Halverson et al., discloses, "the preferable linking agents are azlactone moieties such as those provided by copolymers as taught in US Patent Nos. 4,304,705; 4,451,619; 5,262,484; 5,344,701; and 5,403,902" (Pg. 12, II, 21-24).
- 4. In regard to claims 4, and 5, Halverson et al., teaches, "alternatively, more than one polymeric layer compromising linking agents may be overcoated by a second coating comprising another linking agent coating comprising linking agents" (Pg. 13, II, 30-33).

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- 5. In regard to claim 8, Here, Halverson et al., teaches that the matrix may contain, and with limitation, amino acids, nucleic acids, including oligonucleotides and cDNA, carbohydrates, and proteins such as enzymes and antibodies (Pg. 7, II, 12-15).
- 6. In regard to claims 9-11, Halverson et al., teaches the detection and comparison of molecules transferred to a heat shrinkable film laminate (see Example 17, Pg. 33-35). Halverson et al., discloses that oligonucleotides were hybridized after two hours of incubation and that the samples were detected by fluorescent intensity (Pg. 34, II, 15-35).
- 7. In regards to claim 16, Halverson et al., teaches, a polymeric substrate which includes a major surface having a major surface area and shrinking the polymeric substrate so that the topographical surface area is greater than the projected surface area and as a result a reactant such as DNA which affixed to the major surface of the substrate creating binding sites of the surface area of the majority surface is reduced, thereby increasing the density of the binding sites on the substrate, (Pg. 3-4, II, 30-35 and 1-10 and 24-26).
- 8. In regards to claims 17, as stated above, Halverson et al., teaches method of preparing transferring molecules positioned within a matrix to a laminate comprising:
  - i) a substrate comprising a shrinkable polymeric film, and Here, Halverson et al., states "an elastomeric substrate is stretched and functionalized to create linking agents on the surface of the substrate" (Pg. 4, II, 16-18). Halverson et al., further states "The surface area of the substrate surface may be reduced, thereby increasing the density of the linking agents on the substrate" (Pg. 4, II, 13-

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14). Halverson et al., further states "the arrays of the of the present invention facilitate the affixation of a high concentration of reactant at each binding site, with all the attendant advantages of high density, including the ability to increase detection signal strength. And "an elastomeric substrate is stretched and functionalized to create linking agents on the surface of the substrate" (Pg. 4, II, 16-18, also see Examples 1-6, pp. 20-25)

- ii) a hydrogel disposed on the substrate, to transfer one or ,more molecules from the matrix to the laminate. Here, Halverson et al., states, "In one embodiment of the present invention, array includes a polymeric substrate and a coating comprising linking agents at least partially adhered thereto. (Pg. 3, II, 7-8) and "the high topological surface area arrays are particular useful in this regard. In addition, these high surface area arrays allow sample containing analyte(s) of interest to rapidly come in to contact with reactants, without the necessity of diffusing into a **thick** coating, such as a hydrogel (Pg. 3, II 25-31) and "a heat shrinkable film is functionalized to create linking agents on the surface of the film for subsequent attachment of reactants" (Pg. 4, II, 11-13), especially Examples 6, 11-17). Halverson et al., also states, "that a wide variety of coatings may be suitable for the present invention which encompasses the limitation of the generic term "hydrogel" such as an polyacrylamide gel, (Pg. 12, II, 23-30, and especially see Example 11 and 15).
- 9. In regard to claims 18, 19, and 20, Halverson et al., teaches, "alternatively, more than one polymeric layer compromising linking agents may be overcoated by a second

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coating comprising another linking agent coating comprising linking agents" (Pg. 13, II, 30-33).

- 10. In regard to claim 21, Halverson et al., discloses, "the preferable linking agents are azlactone moieties such as those provided by copolymers as taught in US Patent Nos. 4,304,705; 4,451,619; 5,262,484; 5,344,701; and 5,403,902" (Pg. 12, II, 21-24).
- 11. In regard to claim 23, Here, Halverson et al., teaches that the matrix may contain, and with limitation, amino acids, nucleic acids, including oligonucleotides and cDNA, carbohydrates, and proteins such as enzymes and antibodies (Pg. 7, II, 12-15).
- 12. In regards to claim 24, Halverson et al., also states, "that a wide variety of coatings may be suitable for the present invention which encompasses the limitation of the generic term "hydrogel" such as an agarose or polyacrylamide gel, (Pg. 12, II, 23-30, and especially see Example 11 and 15).
- 13. In regard to claims 25, Halverson et al., teaches the detection and comparison of molecules transferred to a heat shrinkable film laminate (see Example 17, Pg. 33-35). Halverson et al., discloses that oligonucleotides were hybridized after two hours of incubation and that the samples were detected by fluorescent intensity (Pg. 34, II, 15-35).

# Claim Rejections - 35 USC § 103

103(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halverson et al., WO9953319, 21 October 1999 as applied to claims 1-5, 7-11, 16-21,

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and, 23-25 above, and further in view of Kresher, US Patent No. 4,589,965, 20<sup>th</sup> May 1986.

Halverson et al., teaches that in Examples 4 and 5, passive blotting and capillary blotting used to transfer the molecule to the laminate.

Halverson et al., does not teach the application of electro-blotting techniques to the molecule transfers from the matrix to the laminate in this instant application.

Kresher, in contrast does teach the use of electro-blotting techniques for molecule transfer in a gelatin matrix.

It would be *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the method Kresher with the transfer of molecule to film laminates of Halverson since Kresher states "that a rapid and effective method for electro-blotting is provided whereby an electrophoretically resolved material in a gelatin sheet is quickly and effectively transferred to a membrane with high pattern definition and resolution" (Abstract). Kresher further states, "Electro-blotting offers significant advantages over capillary blotting in that the electro-blotting procedure is much quicker." (column 1, II 31-33) and offers the significant advantages such as the molecules in a gel matrix that are relatively inaccessible transfer to the surface allowing for a substantially reduced analysis time (column 1, II 62-64). An ordinary practitioner would have been motivated to use electro-blotting is provided to combine the gel matrix molecule transfers with electro-blotting in order to expedite the production of the coated film laminates.

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### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine L. Maupin; whose telephone number is (703) 308-3617 and fax number is (703) 746-7641.

The examiner is normally in the office between the hours of 9:30 a.m. and 5:30 p.m., and telephone calls either in the morning or the mid-afternoon are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the U.S.P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 308-4242 or (703) 308-2724. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

May 15, 2002

JEFFREY FREDMAN PRIMARY EXAMINER Christine L. Maupin Examiner Art Unit 1637